EXHIBIT F

Aug. 5, 1969 W. H. RING 3,459,184

INTRAVENOUS CATHETER PLACEMENT UNIT

Filed Nov. 4, 1966 2 Sheets-Sheet 1

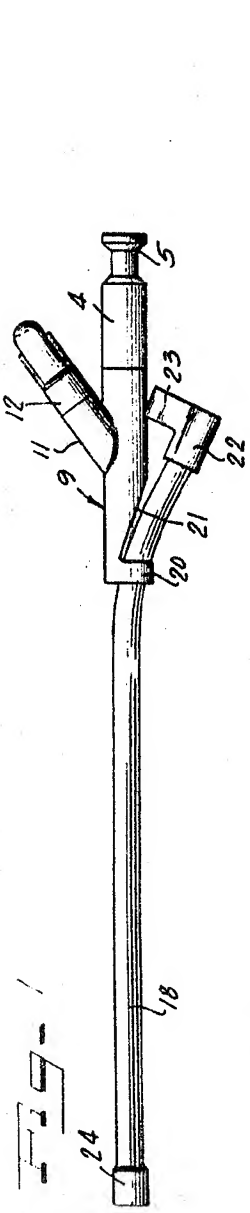

FIG. 1

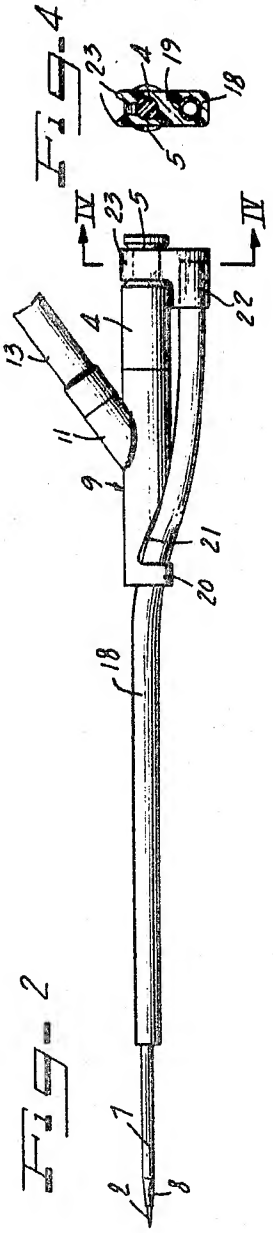

FIG. 2

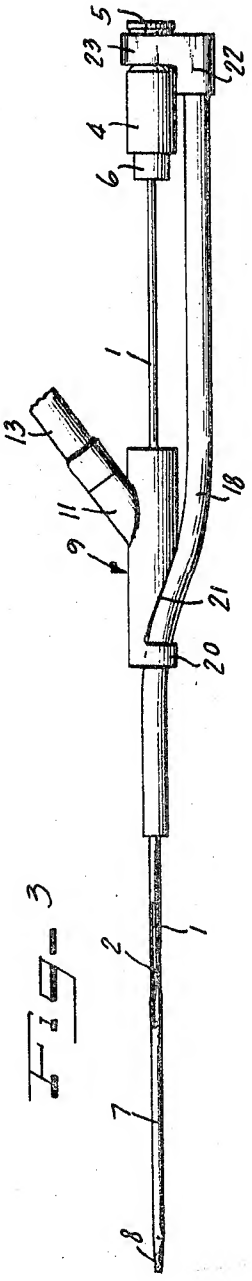

FIG. 3

FIG. 4

INVENTOR.
WALLACE H. RING

BY Hill, Sherman, Meroni, Gross & Simpson ATTORNEYS

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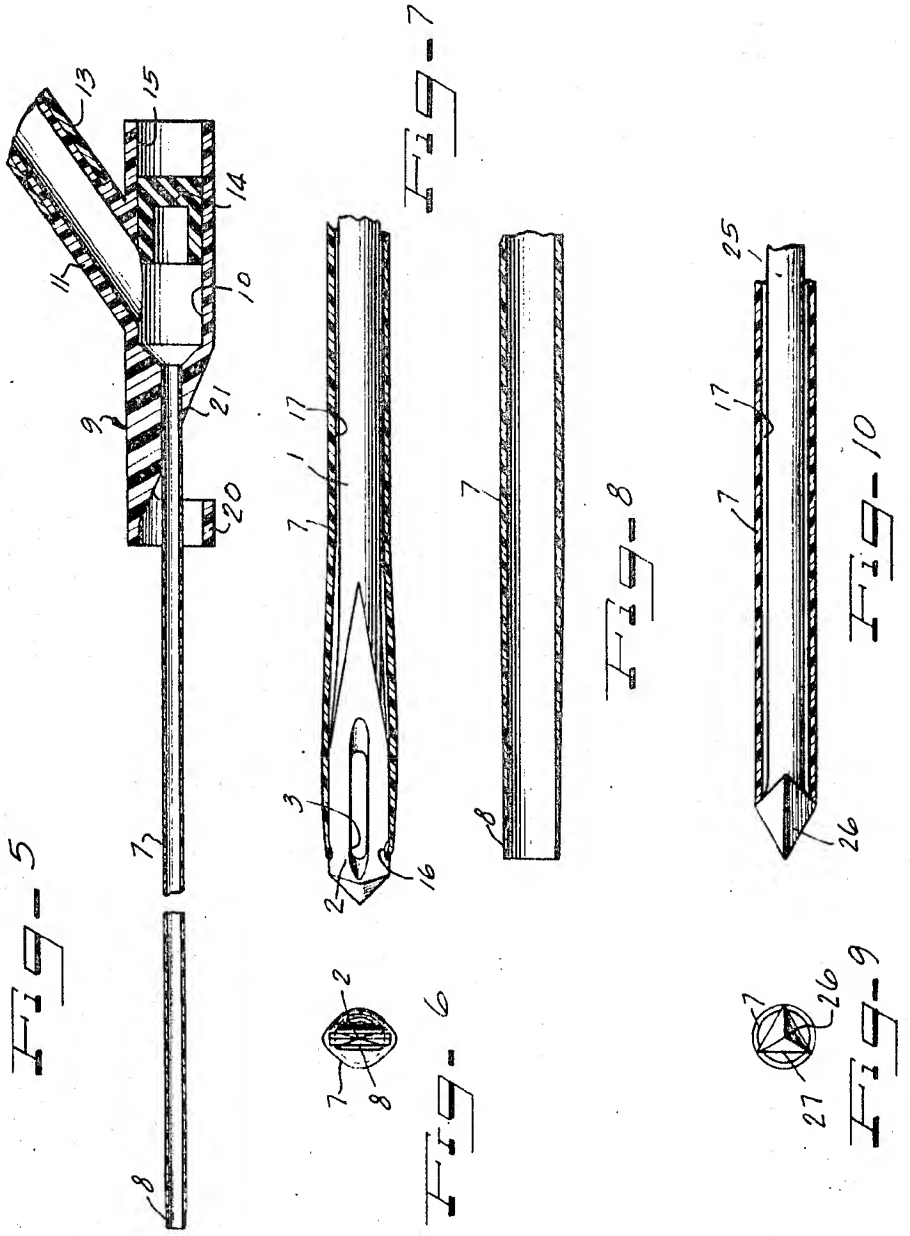

INVENTOR.
WALLACE H. RING

BY Hill, Sherman, Meroni, Gross & Simpson ATTORNEYS

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INTRAVENOUS CATHETER PLACEMENT UNIT

Wallace H. Ring, Salt Lake City, Utah, assignor to Le Voy's Inc., a corporation of Utah

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U.S. Cl. 128—214.4 5 Claims

ABSTRACT OF THE DISCLOSURE

A unit for placing a catheter in a body lumen with the aid of a needle, both catheter and needle remaining in a sterile sheath until properly and completely positioned with the body lumen, whereby no sterile field of operation is necessary, and with which unit both the sheath and needle are completely removable after placement of the catheter leaving only a fitting which connects the catheter to a source of infusion remaining for attachment to the patient's body.

Many times it is desirable to place a catheter in a body lumen with the aid of a solid needle around which the catheter is disposed to obtain the advantages of easier cutaneous perforation, avoid leakage of blood or infusion liquid, and to have the catheter completely filling the cutaneous puncture, which advantages are not often obtainable by using a cannulated needle telescopically associated with the catheter. In the past, however, catheter placement units embodying a catheter telescopically associated with a solid needle were objectionably limited as to the length of catheter that could be utilized, because the catheter was advanced along with the needle into the body lumen to its desired extent, and thereafter the needle withdrawn from the already advanced catheter. A needle over 2½ inches in length is difficult to hold and direct in performing a venipuncture, without danger of contamination of the needle, and if a longer needle is gripped near the proximal end thereof, there is danger of injury to the patient by virtue of the needle bending during venipuncture. Also, it is not desirable in most cases to insert any longer needle into a vein or other body lumen because of the danger of puncturing the lumen wall. Further, with devices of this character as heretofore made, the catheter was not advanced into the body lumen relatively to the needle, and the catheter could not be advanced into the body lumen while infusion takes place.

With the foregoing in mind, it is an important object of the instant invention to provide a catheter placement unit utilizing a solid needle telescopically associated with a catheter so arranged that the catheter may be advanced into a body lumen relatively to the needle while infusion takes place to substantially any desirable extent, even to the vicinity of the heart for the determination of central venus pressure, by virtue of the fact that the unit may be made in any desirable length and facilely used without endangering the patient.

Another important object of this invention is the provision of a catheter placement unit embodying a solid needle and catheter telescopically associated, which unit may be made with a catheter of any desirable length, and both the catheter and needle being maintained in a sterile condition until the catheter is completely advanced into a body lumen.

It is also an object of this invention to provide a catheter placement unit embodying a solid needle and the arrangement between the catheter and needle being such that a flow of blood will be visible in the catheter when a venipuncture has been accomplished so that the operator will know that the tip of the catheter is within the body lumen of a patient.

A further object of this invention resides in the provision of a catheter placement unit embodying a solid needle and a catheter of substantially any desired length, the catheter and needle being enclosed within a sterile sheath, and means are provided for locking the sheath and needle together so that after advancement of the catheter, both the needle and sheath are easily withdrawn, leaving only the catheter extending into the body lumen of a patient and the connection between that catheter and the infusion system.

While some of the more salient features, characteristics and advantages of the instant invention have been above pointed out, others will become apparent from the following disclosures, taken in conjunction with the accompanying drawings, in which:

FIGURE 1 is a side elevational view of a catheter placement unit embodying principles of the instant invention, as the same appears when first removed from a wrapper for use;

FIGURE 2 is a fragmentary view of the placement unit adjusted for the making of a venipuncture;

FIGURE 3 is a fragmentary side elevational view, with parts broken away, illustrating the advancement of the catheter into a body lumen;

FIGURE 4 is a vertical sectional view taken substantially as indicated by the line IV—IV of FIGURE 2, looking in the direction of the arrows;

FIGURE 5 is a central vertical sectional view of only the catheter and the advancer-fitting for connecting the same to the infusion system;

FIGURE 6 is a greatly enlarged end elevation of the needle head and catheter;

FIGURE 7 is a greatly enlarged fragmentary view, with the catheter in section, showing the relationship of the catheter with the needle head;

FIGURE 8 is a fragmentary vertical sectional view of the catheter alone;

FIGURE 9 is an end elevational view showing the relationship between the catheter and a needle head of different form; and

FIGURE 10 is a fragmentary view showing the association of the catheter with the needle, the catheter being shown in section.

As shown in the drawings:

The illustrated embodiment of the instant invention seen in FIGURES 1 to 8 inclusive, includes a solid needle **1** having a flattened spearhead **2** on the distal end thereof to enable easy piercing, as best seen in FIGURES 6 and 7. An elongated, axially extending slot **3** is provided in the spearhead **2** to enable blood to enter the catheter at the time of venipuncture. At the proximal end thereof the needle is provided with a hub **4** which may readily be molded with a suitable plastic, such as nylon, polyethylene, or any other suitable material. The needle end is firmly embedded and secured within the hub **4**. The outer end of the hub is provided with an annular groove **5** therein reducing the diameter of the hub at that point for later engagement by another portion of the placement unit, as will later appear. The inner end of the hub is also reduced in diameter as indicated at **6** for telescopic engagement with the advancer-fitting on the catheter.

Telescopically associated with the needle **1** is a catheter **7** formed from any suitable transparent plastic material. As seen best in FIGURE 8, the internal diameter of the catheter is preferably constant throughout the length of the catheter, but the distal end of the catheter is tapered from the outside so that the wall thins to a narrow edge defining the distal end of the catheter, as indicated at **8**.

As seen best in FIGURE 5, the proximal end of the catheter is fused or otherwise firmly secured within the bore of a tubular fitting, generally indicated by numeral

9, which fitting functions both as a means for advancing the catheter and also as a means of connecting the catheter to an infusion system. The outer portion of the fitting 9 is interiorly enlarged to provide a passage or chamber 10 in communication with the catheter. The fitting also includes a tubular nipple 11 extending upwardly at an angle to the body of the fitting. The inner end of the nipple 11 communicates directly with the aforesaid chamber 10, and the outer end initially is closed by a removable cap 12 until the placement unit is put to use when the cap is removed and the nipple is connected to an infusion tube 13 leading from a source of infusion liquid. The cap 12 maintains the sterility of the interior of the fitting until it is desired to place the catheter. Within the chamber 10 outward of the communication with the nipple 11 a plug 14 of self-sealing material is firmly secured, this plug being satisfactorily made of soft rubber. As seen in FIGURE 5, the plug is so disposed as to leave a recess 15 outward thereof for the reception of the smaller inner end 6 on the needle hub.

When the catheter and fitting arrangement is assembled with the needle, the needle extends centrally through the plug 14, the chamber 10, and through the catheter with the spearhead of the needle projecting just beyond the distal end of the catheter as seen in FIGURES 2 and 7, in the illustrated embodiment of the invention. Initially, before usage, the end portion 6 of the needle hub is seated within the recess 15 in the catheter fitting.

With reference to FIGURE 7, it will be seen that the reduced distal end 8 of the catheter terminates adjacent the point of the needle but beyond the widest part of the needle spearhead 2, flexibility of the catheter permitting it to be distorted to correspond with the shape of the spearhead, as seen best in FIGURE 6. Upon insertion into a body lumen with the needle withdrawn, the inherent resiliency of the catheter will restore the end portion 8 to its original circular shape. If so desired, the needle may be provided with opposed notches 16, as seen in FIGURE 7, to receive the distal end of the catheter to better maintain the catheter and needle in their relative positions until venipuncture has been accomplished.

It will be noted that the slot 3 in the needle spearhead extends toward the point of the needle beyond the end of the catheter so that when venipuncture is made blood may enter the catheter by way of the slot 3. Also, as seen in FIGURE 7 the catheter has an inside diameter slightly larger than the diameter of the needle, thus providing a space 17 to receive blood and make known to the operator that the catheter has properly entered a body lumen.

The catheter and needle are maintained in a sterile condition by a sheath 18 having a slit, indicated at 19 in FIGURE 4, extending lengthwise of the sheath along the top side thereof. The sheath is made from a suitable plastic material, such as polyethylene, and no sealing means are required at the slit, since the resiliency of the sheath tends to maintain the slit closed. The sheath is also transparent, and while sufficiently flexible for the intended purposes, it is, of course, much more rigid than the catheter. The sheath itself is of the same construction as the sheath illustrated and described in W. H. Ring et al. U.S. Patent No. 3,262,448 dated July 26, 1966. The sheath extends through a loop 20 which may be integrally formed on the end of the catheter fitting 9, and behind that loop the fitting is provided with a downwardly and outwardly inclined surface 21 to cause the sheath to bend away from the catheter and needle during manipulation of the placement unit, as seen in FIGURES 2 and 3, the slit 19 of the sheath opening sufficiently to permit the sheath to be readily drawn off the catheter and needle. At the proximal end thereof, the sheath terminates inside an end plug 22 which is provided with a pair of upstanding confronting tooth-like projections 23 for snap-on and gripping engagement with the needle hub inside the groove 5, as seen in FIGURES 2 and 4. With reference to FIGURE 1, it will be seen that at the outset the distal end of the sheath is covered by a temporary cap 24 for the maintenance of sterility. After the various parts of the placement unit have been sterilized and assembled for packaging, the unit appears as viewed in FIGURE 1 with both the caps 12 and 24 in place and the catheter and needle fully protected by and enclosed within the fitting 9 and the catheter sheath. The catheter sheath is extended so as to extend beyond the needle point, and is uncoupled from the needle hub, the locking teeth 23 being disposed against the underside of the fitting 9 with the catheter sheath in a bent condition.

When it is desired to utilize the placement unit, it is removed from the wrapper, the cap 12 on the fitting nipple 11 removed and the nipple connected to an infusion tube 13. Then the cap 24 is removed and by grasping the plug 22 and holding the fitting, the sheath is pulled outwardly to the position seen in FIGURE 2 and locked to the needle hub as explained above, thus leaving exposed aproximately 1½ inches of the needle and surrounding catheter. If desired, at that time the catheter may be flushed with infusion liquid to clear it of air and any sterilization sediment that might have been in it. Venipuncture may now be made by the operator grasping the needle by squeezing the sheath in the distal portion thereof, so that regardless of the actual length of the needle the operator is utilizing a short length thereof so there is no danger of the needle bending during venipuncture. As soon as venipuncture has been made and revealed to the operator by blood flowing outwardly through the catheter, the needle hub is held and the fitting 9 moved along the needle as indicated in FIGURE 3, to advance the catheter beyond the end of the needle and relatively to the needle. Infusion may be turned on as soon as venipuncture is accomplished, and the catheter is advanced while infusion is taking place, the catheter being internally larger than the needle readily permitting this infusion and the catheter easily flexing during its advancement over the wider part of the needle spearhead. When the catheter is fully advanced, the fitting 9 is held by the operator and by gently pulling upon the needle hub both the needle and the sheath are withdrawn completely away, the self-sealing plug 14 preventing any leakage from the outer end of the fitting 9 during the operation and thereafter. Only the catheter and fitting are left attached to the patient, the fitting being connected to the patient's arm by a suitable piece of adhesive tape or in an equivalent manner. The entire operation may be accomplished without the need of a sterile field and with complete asepsis since the operator's hands never touch anything that enters the patient's body, it being only necessary to appropriately prepare the skin at the venipuncture site. The catheter may be of any length that the physician or surgeon requires. Since the catheter initially overlies and extends beyond the widest portion of the needle head and is supported thereby, there is no danger of the catheter moving relatively to the needle during venipuncture. When the catheter is advanced, with the needle functioning as a stylus, the catheter offers negligible resistance in passing over the widest part of the needle head.

In FIGURES 9 and 10 I have illustrated the placement unit embodying a needle of somewhat different configuration than the needle above described, the exact type of needle point being left to the choice of the physician or surgeon. In this instance a needle 25 is utilized of lesser diameter than the inside diameter of the catheter 7, leaving the space 17 between the catheter and the needle. The needle has a triangular head 26 facetted to a point, and the catheter terminates just to the rear of the points of the triangle so that it projects laterally from the needle from the sides of the triangular head as indicated at 27 in FIGURE 9. In this instance, the needle head protects the catheter during venipuncture so there is no relative movement between them, and when it is desired to advance the catheter very little pressure is required to cause the

catherer to assume the shape of the needle head in general and pass over the points of the triangular head. The structure of FIGURES 9 and 10 is utilized in the same manner above described.

Various forms of needle heads may be used, the physician or surgeon having a wide choice in this regard.

It will be understood that modifications and variations may be effected without departing from the scope of the novel concepts of the present invention.

I claim as my invention:

1. In a catherer placement unit,
an elongated needle,
a hub on the proximal end of said needle,
a catherer telescopically surrounding said needle,
a sheath longitudinally slit and more rigid than said catherer enclosing said catheter and needle,
an advancer-fitting connected to the proximal end of said catheter to connect the catheter to an infusion system and advance the catheter relatively to said needle and through which said needle extends,
said sheath being withdrawable to expose a sufficient portion of the catheter and needle for entering a body lumen, and
interlocking means on said needle hub and the proximal end of said sheath operable upon partial withdrawal of said sheath for joint removal with said needle.

2. The catheter placement unit of claim 1, including means on said advancer-fitting slidable along said sheath to maintain said advancer-fitting in alignment with said needle.

3. The catheter placement unit of claim 1, including a loop on the distal end of said advancer-fitting embracing said sheath to maintain proper alignment of said advancer-fitting.

4. The catheter placement unit of claim 3, including a downwardly and outwardly inclined surface on said advancer-fitting proximally of said loop to cause said sheath to bend away from said catheter and needle during advancement of the catheter.

5. The catheter placement unit of claim 1, wherein said interlocking means include said needle hub having a groove therein, and a plug on the end of said sheath having spaced projections for snap-on engagement in said groove.

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DALTON L. TRULUCK, Primary Examiner

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128—221